From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Fall 1995 Volume 2, Issue 3

From the Editor…

Each certified mammography facility receives a copy of **Mammography Matters** *addressed to the individual whose name is on the accreditation application. If you are that person, please route this copy to the technologists, interpreting physicians, and medical physicists in your facility. (See the preprinted routing slip on the back cover of this issue.)*

We also want to reiterate a previous warning. If you read or hear something about MQSA by someone not authorized to speak for FDA, we can't be responsible for its accuracy. We try to work closely with professional associations and journals and review their MQSA articles for accuracy, but we've heard of some instances where incorrect information has been published or presented. If you read or hear something you believe is incorrect, please let us know and we'll set the record straight. Send that information or your comments to:

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

Fax: 301-594-3306

We'd also like to hear your ideas on how we can improve and streamline MQSA inspections. Address inspection comments to:

Mammography Quality Assurance Program
Food and Drug Administration
P.O. Box 6057
Columbia, MD 21045-6057

Fax: 410-290-6351

Analysis of Early Inspection Data Reveals Good News

Analysis of data collected from about 4,200 facility inspections is beginning to reveal how well facilities are meeting the MQSA quality standards. Early indications are promising, with the vast majority of facilities avoiding the most serious Level 1 findings. And at least 30 percent are in full compliance with MQSA. That's good news!

Early indications are promising, with the vast majority of facilities avoiding the most serious Level 1 findings. And at least 30 percent are in full compliance with MQSA.

One of the areas in which most facilities are in compliance is that of radiation dose to the average breast. The dose limits (expressed in millirads, or mrad) are a vital part of MQSA because they provide assurance that patients won't be exposed to unnecessary radiation. The data on dose show that:

- All facilities had doses lower than 400 mrad (a dose level higher than this would be a Level 1 violation).
- Only two facilities have been cited for a Level 2 dose violation (between 350 and 400 mrad).
- The average dose was about 140 mrad.

Also, we have validated very few citations for the Level 1 areas listed below:

- Only four facilities severely failed the phantom image score (less than three fibers, two masses, or two speck groups).
- Only four had no system for sending reports to referring health care providers or self-referred women.
- Only two failed to maintain patient records.
- Only one lacked processor QC records.

Almost all facilities had a medical audit and outcomes analysis system in place, were accredited and certified, and were using equipment specifically designed for mammography.

These numbers indicate that most of you are diligently pursuing quality mammography and that your efforts are paying off.

Problem Areas

Level 1 findings are the most serious because they may seriously compromise the quality of a facility's

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From the Director . . .

Is MQSA really making a difference? This is a good question, as the goal of the program is to improve mammography quality. In striving to meet this goal, we know that we need to balance questions of cost, availability of services, and judicious use of regulatory authority regarding the practice of medicine. Preliminary data are being gathered as part of our own evaluation of our work. Thus far we think that most of the impact of the MQSA program is positive.

The area in which we have seen the most change is accreditation. Before MQSA, only about 46 percent of facilities were accredited. Now every mammography facility must undergo and pass accreditation.

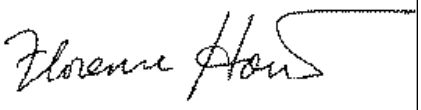
As a test for quality, state accreditation bodies and the American College of Radiology have rigorously evaluated clinical and phantom images. Many facilities benefitted from recommendations made by the accreditation bodies as a result of clinical image review and became accredited and certified. The majority of facilities that failed accreditation decided to correct problems and reapply (roughly 400 out of 565 facilities, or about 70 percent).

Other areas of encouragement are found in our inspection data. In 1988 and 1992, FDA and the states evaluated phantom image scores nationwide. In 1988, 85 percent of facilities surveyed had an acceptable phantom image score. In 1992, 89 percent had an acceptable score. Today, under MQSA, the gradual improvement of phantom score has skyrocketed, with 98 percent now acceptable.

Darkroom fog is another area that has shown remarkable improvement. Details are presented in the "Technical Corner" in this issue of Mammography Matters.

This preliminary news should really make you very proud. It means that, as a nation, we are all performing better mammography so all women who have mammograms, no matter where they live, have greater assurance that, if they have breast cancer, it will be detected early and their lives can be saved.

Keep up the good work!



Florence Houn, M.D., M.P.H.
Director, Division of Mammography Quality and Radiation Programs

Accreditation, Certification, and Commercial Products

FDA neither endorses nor requires the use of any specific x-ray system component, measuring device, software package, or other commercial product as a condition for accreditation or certification under MQSA.

Any representations, either orally or in sales literature, or in any other form, that purchase of a particular product is required in order to be accredited or certified under MQSA should be reported to FDA immediately so that appropriate action may be taken.

FDA Begins Billing for Inspections

Soon after gaining the required approval for the governmental entity declaration form, FDA began sending invoices for MQSA annual inspections. (Refer to the Summer 1995 issue of *Mammography Matters* for the definition of "governmental entities.")

To pay your fee, mail your payment via the U.S. Postal Service. Checks should be made payable to the order of FDA MQSA Program; any check or bank draft should be drawn on, or payable through, U.S. financial institutions located in the United States. If you pay by means other than a U.S. postal money order, FDA will not consider your payment made until the check or bank draft has been cleared and the dollar amount received by FDA. Under MQSA, FDA has no authority to waive inspection fees.

If a facility fails to pay in full within 30 days of the date of the invoice, FDA will:

- Charge interest at a rate of 14 percent per year.
- Assess a $20 administrative fee for delinquent invoices over $100 for each full 30-day period during which the account remains outstanding.
- Charge an additional current late payment penalty for all payments not made within 90 days.

If a facility fails to pay the inspection fee (or reinspection fee, where applicable), FDA will report this debt to credit-reporting agencies. Further, if a facility still has not paid its fee within 90 days after the due date, FDA will forward the account to a collection agency or the U.S. Department of Justice for enforced collection.

Instructions regarding payment are printed on the reverse side of the inspection fee billing form. Please follow them carefully and include all requested information.

Also, remember that it is essential that you report any change of address to your accreditation body immediately so it can update its records and transmit the changes to FDA. Once the changes are entered into the database, FDA will automatically transmit them to the Health Care Financing Administration for Medicare reimbursement purposes.

If you have questions about your invoice, contact FDA by one of the following methods:

Address:
Mammography Quality Assurance Program
Food and Drug Administration
P.O. Box 6057
Columbia, MD 21045-6057

Fax: 410-290-6351
Phone: 800-838-7715

If you have questions regarding the findings of your inspection, contact the FDA-contracted state agency that conducted the inspection.

Mobile Facilities: An Option To Reduce Costs

Owners of multiple mobile mammography units operating under two or more FDA certificates have an option to reduce their total inspection fee. For inspection purposes only, they may "combine" their "facilities" to reduce inspection costs.

The following conditions must be met to qualify for the reduced fee:

- ALL mobile units must use either on-board film processing or centralized processing at the inspection site.
- ALL records—quality control, personnel qualification, and medical records—used for all units in the group at all sites serviced by the mobile unit must be available at the inspection site at the time of the inspection.

Facilities meeting the above conditions are charged using the following equation:

Total inspection fee = $1,178 + [(n - 1) x $152], where n = total number of units inspected.

If you own or operate multiple mobile units, please inform the inspector at the time of the initial appointment call.

Analysis Reveals Good News

Continued from page 1

mammography services. Facilities with valid Level 1 findings will receive a Warning Letter from FDA and must respond to it. The percentages of inspected facilities for the most common initial Level 1 findings, in order of decreasing frequency, are listed below. (Note that the percentages don't add up to 100 because not all findings are listed; also, a given facility may have more than one type of finding.)

- Lack of adequate qualifications for interpreting physicians:
  - No board certification and the required 2 months of initial training (1.2%)
  - No state license (0.5%)
- Lack of adequate qualifications for medical physicists (1.2%)
- No medical physicist survey within the past 14 months (0.6%)
- Lack of adequate qualifications for radiologic technologists: no license or certification (0.4%).

Inspections Show Improvement

A comparison of preliminary inspection data from July 1995 and current data as of October 1995 shows that we're finding fewer instances of noncompliance with MQSA standards. Here's a recap of the percentages of facilities with no findings and with Levels 1, 2, and 3 as their highest level finding.

	JULY 1995 (%)	OCTOBER 1995 (%)
No non-compliances:	15	32.5
Level 3:	54	48.6
Level 2:	25	15.8
Level 1:	6	3.1

Although Level 2 and Level 3 findings are considered less serious than Level 1 findings, they must be corrected. Level 2 findings require that the facility send FDA a response within 30 days of receiving the inspection report. The following are the most common Level 2 findings, again in order of decreasing frequency:

- Interpreting physician requirements:
  - Less than 40 hours of CME (7.4%)
  - Inadequate initial experience (5.9%)
- No documented corrective action for processor quality control problems (7.6%)
- Film underprocessing (4.2%)
- Quality control charts missing 30 percent or more of the time (3.7%)
- Fog levels exceeding 0.10 (3.4%).

Level 3 findings are the most common type of citation. Many Level 3 findings relate to the medical physicist survey report. Here's what our data show about some Level 3 findings, in order of decreasing frequency:

- Incomplete physicist evaluation of x-ray system assembly (8%)
- Incomplete physicist evaluation of technologist quality control activities (7.5%)
- Fog levels between 0.07 and 0.09 (4.6%).

Level 3 findings will be checked at the facility's next inspection.

Appealing an Inspection Finding

FDA reviews all inspection reports with Level 1 findings. In some cases, FDA may not validate the inspector's findings.

If a facility disagrees with the findings listed on the inspection report, it may appeal to the FDA District Office that performed the review. The name and address for that office appear on the document titled, "How To Interpret the Inspection Report and Respond to FDA," which accompanies the inspection report.

If a facility wishes to dispute a Warning Letter (for a Level 1 finding), it should address its response to the individual identified in the letter.

If a facility that receives a Warning Letter fails to cooperate with FDA and to make the necessary corrections, the agency may issue a Directed Plan of Correction, which is a sanction under MQSA. If a facility wishes to appeal this action, it should contact the Director, DMQRP, at the Rockville, MD, address listed in the "From the Editor" column on page 1.

Prepare for Your Upcoming Inspection, but Don't Lose Sleep

According to our inspectors, the staff at many facilities are unnecessarily apprehensive when inspectors arrive for an MQSA inspection. Please be assured that if you're performing quality mammography, have all the necessary records available for the inspector to see, and are honest in your dealings with FDA, your inspection should go smoothly.

A Word of Warning

Facilities that are trying to perform quality mammography and are honest about their practices and documentation should be able to avoid civil and criminal penalties. However, FDA has mechanisms in place to deal with offenders who misrepresent facts or falsify records.

Knowingly providing false information within the jurisdiction of a U.S. agency can result in criminal liability, punishable by up to $10,000

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Technical Corner

Orhan Suleiman, Ph.D., Chief, Radiation Programs Branch, Division of Mammography Quality and Radiation Programs, provided information for the following article.

Darkroom Fog

To ensure optimal reading of mammography films, the darkroom must be safe from sources that may fog the film. Although the effect of fog on x-ray film is usually subtle, fog can degrade image quality to the extent that the exam must be repeated. Fog also reduces contrast and results in unpredictable variations in film density.

MQSA Requirements

The interim MQSA regulations adopted the fog levels specified in the American College of Radiology (ACR) Mammography Quality Control Manual. MQSA inspectors check against the 1994 ACR specification, which is a maximum optical density of 0.05 when the film is exposed in the darkroom for 2 minutes. (The 1992 ACR Manual specified an optical density of 0.02 or less. This limit, however, proved to be too restrictive, so the requirement was relaxed in the 1994 Manual.)

Fog Levels Before MQSA

A survey of diagnostic radiology darkrooms in the early 1980s showed that only 36 percent would have met the 0.05 fog limit. A 1992 survey of mammography facilities (before MQSA went into effect) showed that 38 percent would have met this limit. Results of MQSA inspections conducted since January 1995, however, indicate that 89 percent of facilities are now within the specified limits. These results, shown in the chart, are encouraging and suggest that the program is working.

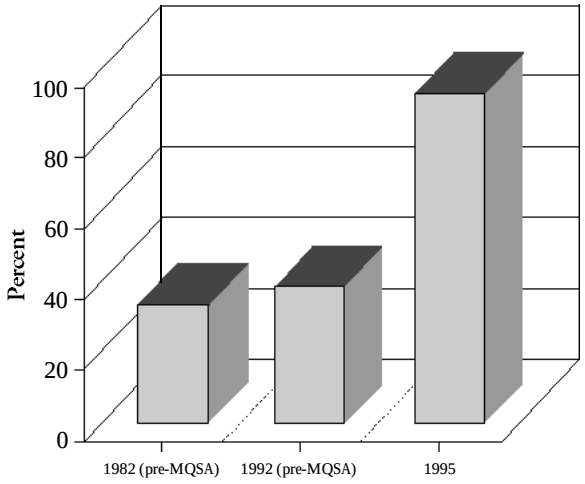
Orhan H. Suleiman, Ph.D., Chief, Radiation Programs Branch

Hints To Help You Comply

If you use the appropriate safelight filters at the distance and with bulbs of the wattage recommended by the film manufacturer, you should be able to meet the 0.05 fog optical density limit. We suggest you write on the filter the date the safelights are installed, using an opaque, permanent marker. Some safelight filter manufacturers recommend that the filter be replaced quarterly. This, however, is usually unnecessary if the darkroom passes the fog test.

If your darkroom fog level exceeds 0.05, you should look for and correct the sources of fog, which may include:

- Incorrect or faded safelight filters
- Cracked filters or safelight housing
- Safelights too close to the film handling area
- Incorrect light bulb wattage
- Indicator lights, such as those on processors and timers
- Light leaks around processors, doors, and passboxes
- Light leaks through perforated ceiling tiles or incorrectly placed tiles in suspended ceilings.



Facilities Meeting MQSA Fog Levels (≤0.05)

Q & A

Q & A is a regular column in **Mammography Matters.** *We welcome your questions and will publish answers to any that are of general interest. Send your questions to* **Mammography Matters,** *FDA/CDRH (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850, fax 301-594-3306.*

Q Does FDA endorse any publications?

A The only mammography publications that have the force of law are those that appear in the *Federal Register* and in the 1992 and 1994 ACR Manuals, which were adopted as part of the interim MQSA regulations. We do author some journal articles and, when asked, we review articles and books on mammography written by others. However, if the material isn't authored by FDA personnel, we can't vouch for its accuracy.

Q I'm confused by the numbers I've heard about the number of CEUs a technologist must earn in mammography. One source tells me 40 CEUs, another 5 per year, and another 15 over 3 years. Which is correct?

A All are right, but they apply to different situations or at least to different ways of stating the requirement.

One of the initial qualifications technologists must meet is to have training in mammography; until October 1, 1996, a year of experience can be substituted. On the advice of the National Mammography Quality Assurance Advisory Committee, we established a policy that any technologist who has earned 40 CEUs in mammography, or the equivalent, is considered to have adequate training. If the technologist earned less than 40 CEUs, the training may still be adequate but the inspector will make that determination on a case-by-case basis.

Thus, the 40 CEUs are an option for meeting the initial qualification requirement. On the other hand, the 5 CEU figure is a continuing requirement. Beginning on October 1, 1994, or whenever the technologist completed the initial qualifications, whichever date is later, he or she must earn an average of at least 5 CEUs in mammography per year.

As a policy, we've decided to allow a "grace period" of 3 years for the continuing education requirement. During this period, if inspectors find a technologist who has not maintained the requisite number of CEUs, the technologist will be given a friendly reminder but not cited. However, by the end of the grace period, the technologist must have earned at least 15 CEUs for an average of at least 5 CEUs over the 3-year period. This, then, is where the 15 CEU figure comes from. The American College of Radiology, in their voluntary accreditation program, also requires 15 CEUs every 3 years, which is another possible source of that number.

Q Under what conditions can technologists use the reading of journal articles to meet MQSA initial and continuing education requirements?

A FDA's policy, based on that of the American Registry of Radiologic Technologists, is to accept CEUs earned by reading articles as a means of meeting the technologist educational requirements. The articles, however, must be approved and the number of CEUs determined by the sponsoring organization, not the reader. The reader also must take and pass an examination on the material.

Q In rural areas, facilities sometimes have to use "temporary radiologists" to read mammograms when the permanent radiologists are on vacation. If these temporary radiologists don't meet the 40 mammograms per month requirement, are they allowed to read mammograms under MQSA?

A No. The MQSA personnel requirements apply to everyone who provides mammography services.

Q In reporting results of a mammogram, what requirements does a facility have to meet?

A Each facility must prepare a written report of the results of any mammography exam as soon as reasonably possible. The report must have the name of the interpreting physician and be provided to the examinee's referring physician, if any. If the examinee is self-referred, the report must be sent directly to the patient. In that case, it must include a summary

Q & A *(continued)*

written in language easily understood by a lay person.

Q What does "signed by an interpreting physician" mean? Is an actual signature required?

A The interpreting physician is not required to hand-sign the mammography report. FDA only mandates that the name of the interpreting physician who has seen and read the mammography be on the report to identify who is responsible for the interpretation. The minimum requirement is that the first initial and last name appear on the report.

Q Does MQSA require that the name of the technologist performing the mammogram be included in the written interpretation?

A No.

Q May examinees keep their own films and reports?

A Yes. They also can request a facility to transfer records permanently to another facility, medical institution, physician, or themself. Temporary transfer to other facilities for comparison of old and current films is not addressed under the current regulations. Therefore, facility procedures for such transfers may vary.

Q Do FDA regulations bar self-referrals?

A No. Anyone who says MQSA bars self-referrals is misinformed. On the other hand, facilities are not required to accept self-referrals. The interim regulations, however, do require that if an examinee is self-referred and has no health care provider, the facility must provide her with a written report of the exam, including a summary written in terms easily understood by a lay person.

Q Under what circumstances do examinees receive the mammography report?

A Under MQSA, self-referred examinees who do not have a referring physician should get the mammography report AND a lay summary of the report. This permits a self-referred woman who later acquires a primary care physician to give her new physician her latest mammography results.

Q Our facility asks patients to sign a consent form to obtain medical information, such as biopsy results, from surgeons and referring physicians. This is part of our tracking system and medical outcomes audit. What do I do if the patient refuses to sign?

A You aren't required to do anything because there's no requirement for patients or referring physicians to participate in a facility's outcomes audit. You won't be cited for failure to obtain this information.

MQSA requires all facilities to have a tracking system to allow analysis of medical outcomes as part of a quality assurance program for clinical interpretation.

Currently, FDA inspectors check to ensure that all positive mammograms are entered into the system and that attempts to obtain pathology information are made. This information may not be available for a variety of reasons, including the patient or referring physician not wishing to divulge the information. Nevertheless, facilities that take the time to explain the benefits of tracking as it pertains to quality assurance often find that patients and physicians are willing to cooperate.

Look for MQSA on the Internet

Look for MQSA information soon on FDA's home page on the Internet. Find us at http://www.fda.gov in the "Medical Devices and Radiological Health," "Program Areas" sub-pages. Besides *Mammography Matters* and other educational documents, we will include *Federal Register* notices, press releases, and other relevant information.

Analysis Reveals Good News

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and imprisonment of up to 5 years, or civil liability under MQSA, or both. Civil sanctions (fines) also apply if a facility fails to obtain a certificate or to comply substantially with established standards, or if facility personnel aid and abet in a violation of the standards. In addition, a facility can have its certificate suspended or revoked and be barred from applying for reinstatement for at least 2 years.

Instances of suspected fraud are referred to FDA's Office of Criminal Investigation. That office, in turn, determines whether the matter should be referred to the Justice Department. When a U.S. court issues a sanction, appeals are permitted within the limits of the judicial system.

The mention or illustration of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by FDA.

Mammography Matters is a quarterly publication of the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Its purpose is to help mammography facilities comply with the requirements of the Mammography Quality Standards Act of 1992. It is distributed to mammography facilities and other interested organizations and individuals.

Articles may be reproduced or adapted for other publications. Comments should be addressed to:

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

Fax 301-594-3306.

Florence Houn, M.D., M.P.H., Director, DMQRP, CDRH

Carole Sierka, Managing Editor; Chief, Outreach Staff, DMQRP, CDRH

Mickie Kivel, Editor, DMQRP, CDRH

Other contributors: Wally Mourad, Orhan Suleiman

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration (HFZ-240)
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

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